

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s):	Heyduk et al.	Art Unit	1635
Serial No.:	10/539,107	Examiner:	Richard A Schnizer
Filed:	June 15, 2005	Conf. No.	2295
For:	BIOSENSORS FOR DETECTING MACROMOLECULES AND OTHER ANALYTES		

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

This letter is in response to the Office Action dated March 16, 2007, in which Applicant was requested to elect a single biosensor having 2 or more epitope binding agents selected from the species: antibody/antibody, antibody/aptamer, antibody/dsNA, aptamer/aptamer, aptamer/dsDNA, dsNA/dsNA, antibody/antibody/antibody, antibody/antibody/aptamer, antibody/antibody/dsNA, antibody/aptamer/dsNA, aptamer/aptamer/aptamer, aptamer/aptamer/antibody, aptamer/aptamer/dsNA, dsNA/dsNA/dsNA, dsNA/dsNA/antibody, and dsNA/dsNA/aptamer, for prosecution on the merits.

Applications filed under 35 U.S.C. §371 are subject to an election if they lack "unity of invention." PCT Rule 13.1 defines unity of invention as "a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features." Rule 13.2 defines "special technical features" as "a contribution which each of the inventions, considered as a whole, makes over the prior art."

In this application, election of species is not proper because the species share a special technical feature. As the examiner acknowledges<sup>1</sup>, each of the species listed above are epitope binding agents, and therefore they share the special technical feature of being “capable of binding to a specific epitope of an antigen, a polypeptide, a protein or a macromolecular complex,” as defined in paragraph [00119] of the specification. This special technical feature, in combination with the rest of the biosensor claimed, defines in part, the biosensor over the prior art. Because the species share the special technical feature of being epitope binding agents, there is unity of invention under PCT Rule 13.1, and Applicant should not have to elect a single species.

The Office states that “the species lack the same or corresponding special technical features for the following reasons: the epitope binding agents are from different art-recognized classes of molecules.”<sup>2</sup> This is not a proper basis for requiring a species election. MPEP §1850(II) specifically states that a lack of unity rejection should not be raised “*merely because the inventions claimed are classified in separate classification groups...*”

Moreover, the MPEP states “no problem arises in the case of a genus/species situation” when the “genus claim is directed only to alternatives of a similar nature.”<sup>3</sup> The phrase “alternatives of a similar nature,” as used in reference to chemical compounds, is defined in MPEP §1850(III)(B). Alternatives will be similar in nature if two criteria are met. First, “[a]ll alternatives have a common property or activity.”<sup>4</sup> As discussed above, each species listed by the examiner has the common property of being an epitope binding agent. Second, “[a] common structure is present ... or, [i]n cases where the common structure cannot be the unifying criteria, *all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.*”<sup>5</sup> In the present case, the examiner focused on the lack of a common structural element, but did not proceed to the second option where “all alternative belong to a recognized

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<sup>1</sup> Page 3 of the Office Action mailed 3/16/2007.

<sup>2</sup> *Id.*

<sup>3</sup> MPEP §1850(II).

<sup>4</sup> MPEP §1850(III)(B).

<sup>5</sup> MPEP §1850(III)(B).

class of chemical compounds.” “The words ‘recognized class of chemical compounds’ mean “each member could be substituted one for the other, with the expectation that the same intended result would be achieved.”<sup>6</sup> Each of the epitope binding agents may be substituted one for the other, and the same result would be achieved, namely, as the specification dictates, the agent will be capable of binding a specific epitope. Therefore, the epitope binding agents are similar in nature, and “no problem” arises with respect to unity of invention, per MPEP §1850(II).

Consequently, applicant respectfully traverses the species election requirement and requests that all species be examined concurrently.

Alternatively, Applicants, subject to the foregoing traverse, hereby elect the biosensor consisting of two epitope binding agents, wherein each epitope binding agent is an antibody for initial prosecution on the merits.<sup>7</sup> The claims that read on the elected species are claims 109-111, 116, and 118-127.

Applicant reserves the right to request rejoinder of the remaining species upon allowance of a generic claim.

The Commissioner is authorized to charge any fees that might be due to Deposit Account No. 50-1662.

Respectfully submitted,

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Date: April 16, 2007

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<sup>6</sup> MPEP §1850(III)(B).

<sup>7</sup> i.e. the antibody/antibody species